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410.016

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	S.G. Rimell
E. THIBAULT et al	:	
Serial No.: 09/308,195	:	Group: 2175
Filed: May 12, 1999	:	
For: METHOD...PROCESS	:	

Hedman and Costigan
1185 Avenue of the Americas
New York, N.Y. 10036
August 3, 2005

RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Office Action of July 13, 2005, Applicants are submitting herewith a revised brief wherein the 2 independent claims are individually discussed with reference to the specification and drawings. Therefore, it is requested that the Brief be accepted and the Appeal be allowed to proceed with the Examiner providing Applicants with an Examiner's answer or issuance of a Notice of Allowance.

Respectfully submitted,
Hedman and Costigan

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Marie-Louise Pinset

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BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REAL PARTY IN INTEREST

The real party in interest is I.D.M. Immuno-Designed Molecules by way of an assignment which has been recorded in the Patent Office at frame 0980 of reel 10038.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants, the Appellants' legal representative or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF THE CLAIMS

The claims in the application are claims 2 to 8 and 10 to 16, all other claims having been cancelled.

STATUS OF THE AMENDMENTS

The amendment of July 9, 2004 has been entered since it obviates all of the grounds of rejection under 35 USC 112.

PRIOR ART

Killian	WO94/11838	May 19994

The Killian reference is directed to a method of automatically testing biological fluids including a network database holding test protocols and the test results for identified blood samples within a biology testing system but not within a therapeutic process.

SUMMARY OF THE INVENTION

The present invention is directed as can be seen from independent claim 15 to a method for processing information used for quality management in a therapeutic process involving several entities as clearly described on page 3 of the application including an operational entity in a preparation laboratory which method comprises operations of taking cells from a patient specific treatment operation on the cells using a specific treatment protocol and a reinjection operation into the patient of the cells treated in this manner which operations of taking cells treatment and reinjection are subjected to a standard operating procedure for a preparation comprising a series of functional stages for each batch of samples taken from a given patient. After each functional stage, a stage of sequential and conditional validation of the functional stage is effected before passing from one validation stage to a following validation stage being conditional on the results of processing data during the validation stage and on a full completion by an operator of operational instructions within a screen page associated with the functional stage. A stage of processing information and data collected in different validation stages with the collected data being associated with the batch of samples and indicative of operators and of the process state of progress before issuing final certification of a preparation carried out according to the standard operating procedure and a stage for imputing post-injection follow up information and forwarding the information to the operational entity and a system for processing such information.

Independent claim 16 is directed to a system which is illustrated in Fig. 3 and as dismissed beginning in line 32 of page 5 through line 24 of page 6.

THE ISSUES

Claims 2 to 6, 8 and 10 to 16 stand rejected under 35 USC 102 as being anticipated by Killian and claim 7 stands rejected under 35 USC 103 as being obvious over the Killian reference. The Examiner states, with respect to claim 15, that Figure 1 discloses several different entities including an operational entity (data management system 12), preparation laboratory (processing center 16) and treatment laboratory (other processing center 17 or incubation stations 20). The Examiner states that one functional stage in the Killian process is the receipt of a shipment of reagent chemicals with the user following a series of sequential validation steps to validate a received lot of reagents used for blood testing. The steps of Figure 5 of the reference are sequential in the sense that they must be followed in exact order and are conditional in the sense that the subsequent steps cannot be reached until previous steps are completed. After the validation steps are completed, the data entry pages can be closed by simply turning off the computer. The data is processed and entered into a database 88 and the state of progress as to whether or not the steps have been completed and the summary report becomes the final certification. The Examiner alleges that step 86 in Fig. 5 calls for the presentation of an alarm icon and the user requests confirmation of kit components and any of the information entered in Fig. 5 can be read as post-injection information since the information may be entered at any time.

GROUPING OF THE CLAIMS

All of the claims stand or fall together.

APPLICANTS' ARGUMENTS

Applicants respectfully request the Board of Patent Appeals and Interferences to reverse the Examiner's objection since it is deemed that the Killian reference neither anticipates nor renders obvious Applicants' invention.

The Killian reference discloses a system for automatically testing biological fluids including a network database holding test protocols and test results for identified samples. The system implements a method for processing information related to blood samples within a biology testing system but not within a therapeutic process. Moreover, the biological testing system of Killian is not related to a therapeutic process involving a reinjection operation into a patient from whom cells have been collected. The routine for recording master lot information disclosed in lines 20 to 29 of page 25 and lines 1 to 20 of page 26 and illustrated in Figure 5 of the reference includes a succession of steps such as selection data entering and conformation request stages and cannot be assimilated to a standard operating procedure for preparation comprising a series of functional stages.

Moreover, each stage of the routine illustrated by Figure 5 of the reference is not followed by a stage of sequential and conditional validation of the said stage. Therefore, Killian differs from the subject of claim 15 in that it does not relate to a method for processing information used for quality management in a therapeutic process involving several entities optionally remote including an operational entity and a preparation laboratory. It further does not disclose after each functional stage a stage of sequential and conditional validation of the said functional stage with each screen page being closed responsive to a closing order only if all of the operational instructions within the screen page have been carried. It further does not disclose an alarm icon being provided for prompting an operator to consult a screen page listing anomalies detected during the said processing stage and also does not disclose a stage for inputting post-reinjection follow up information and forwarding the said information to said operational entity. Therefore, Killian does not anticipate the subject matter of claims 15 and 16.

With respect to any obviousness type rejection, Killian also does not render obvious Applicants' invention. The system disclosed by Killian is intended to process control for fluid biological testing and not for quality management in a therapeutic process since the Killian system does not include any reinjection stage and is not intended to control a therapeutic process. In fact, Killian is concerned with testing blood samples which is well known to include some destructive treatments applied on a small part of each sample, said tested part being disposed of once the testing is finished. In contrast

thereto, the present invention applies to a modifying treatment applied to the right same cells that will be reinjected into the patient as indicated in line 20 of page 1. It is therefor clear that Killian has objective which totally contradicts the subject matter of Applicants' invention.

Moreover, as illustrated in Figure 5 and quoted by the Examiner, "Some of the steps are also conditional in the sense that they require that "if-then" steps. Steps 74 and 84 are conditional of the steps which involve "if-then" decisions. Indeed, in Killian, these conditional steps 74 and 84 are not blocking steps as in Applicants' invention since the said steps will lead either to step 76, 86 or to steps 84, 78. Therefore, these step features disclosed by Killian totally contradict the subject matter of amended claim 15 as they do not result in the interruption of the process when operational instructions are not carried out. Killian would not teach or suggest to one skilled in the art of quality management in therapeutic processes, the principle of a stage of sequential and conditional validation after each functional stage, the completion of which being a strict condition to the passing from said functional stage to the following stage within a method and system as recited in claim 15.

It should be noted that Applicants' patentable contribution with respect to the Killian reference is clearly patentable thereover. Claims 15 and 16 recite the screen page being closed responsibly to a closing order only if all of the instructions have been

carried out as indicated in lines 24 to 32 of page 10 of the application. Moreover, the claims call for an alarm icon being provided for prompting the operator to consult a screen page listing anomalies detected during the processing stage and these features are not in the Killian reference.

As noted above, the Killian reference discloses automatically testing biological fluids including a network database holding test protocols and the test results for identified samples. The system uses a method for processing information related to blood samples within a biology testing system but not within a therapeutic process. The reference has nothing to do with Applicants' therapeutic process for processing information used for quality management in the therapeutic process. Therefore, the teachings are completely non-analogous to Applicants' invention wherein in the therapeutic process, there is a reinjection operation into a patient from whom the cells have been collected. The routine for recording master lot information disclosed in lines 20 to 29 of page 25 and lines 1 to 20 of page 26 and as illustrated in Figure 5 of the reference includes a succession of steps such as selection data entering and conformation request stages. It cannot be used as the standard operating procedure for preparation comprising a series of functional stages.

Moreover, each stage of the routine of the reference is not followed by a stage of sequential and conditional validation of the said stage. This means that Killian differs

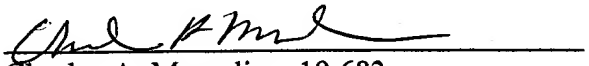
from claim 15 in that it does not relate to a method for processing information used for quality management in a therapeutic process involving several entities including an operational entity and a preparation laboratory. It also does not disclose that after each functional stage, there is a stage of sequential and conditional validation of the functional stage with each screen page being closed responsive to a closing order only if all of the operational instructions within in the screen page have been carried out. It also does not disclose an alarm icon being provided for prompting an operator to consult a screen page listing anomalies detected during the said processing stage and also does not disclose a stage for inputting post-reinjection follow up information and forwarding the information to the operational entity. Therefore, the reference does not anticipate or render obvious the system of claims 15 and 16.

The system disclosed by Kilian is intended to process control for fluid biological testing and not for quality management in a thereapeutic process and the Killian system does not include any reinjection stage and is not intended to control a therapeutic process as in Applicants' invention. Killian is concerned with testing blood samples which is well known to include some destructive treatment supplied on a small portion of each sample, the tested part being disposed of once the testing is completed. In contrast thereto, Applicants' invention applies to a modifying treatment applied to the same cells that will be reinjected into the patient as indicated in line 20 of page 1 and therefore, the Killian objectives are completely different from Applicants'.

CONCLUSION

It is believed that Applicants have complied with all the necessary requisites for the granting of Letters Patent in view of the above and that the reference in no way anticipates or renders obvious Applicants' invention. Therefore, the Board of Patent Appeals and Interferences is respectfully requested to reverse the Examiner's rejections. Three copies of the brief are being filed as well as PTO Form-2038 authorizing the $165.00 fee for filing the appeal brief.

Respectfully submitted,
Hedman and Costigan



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APPENDIX

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The claims on appeal are as follows:

Claim 2

The process according to claim 15, wherein validation of the final certification is conditional on input of a validation password with a computer.

Claim 3

The process according to claim 15, implemented in a data processing system, wherein with each validation step is associated with at least one screen page

PO: a screen page which provides the process operator

PEI: screen page corresponding to a stage of a process number

EP: title

EA: retrospective analysis screen page

EC: certification screen page

EI: anomalies screen page

which can be accessed on a display means of at least one computer workstation connected to said data processing system.

Claim 4

The process according to claim 3, wherein each screen page comprises coded identification field for a patient which matches a batch of samples subjected to the standard operating procedure.

Claim 5

The process according to claim 15 wherein exit from certain stages (RA) of said process is conditional on printing the screen pages (EA) corresponding to these stages.

Claim 6

The process according to claim 15 implemented in a preparation laboratory receiving therapeutic kits from at least one operational entity (EX), wherein it further comprises stages for monitoring the transfer of these kits.

Claim 7

The process according to claim 15 implemented in a preparation laboratory which deals with a cytapheresis service, wherein it further comprises stages for monitoring the receipt of cytapheresis pouches.

Claim 8

The process according to claim 15 implemented in a preparation laboratory which deals with a control laboratory, wherein it further comprises stages for processing results of control tests carried out on each batch of samples.

Claim 10

A system according to claim 16, implemented in a preparation laboratory, designed to execute management tasks of a preparation laboratory number n within this laboratory.

Claim 11

A system according to claim 16, wherein it is connected to a communications network to exchange data with other entities selected from the group consisting of: treatment centers number n, cytapheresis services number n, collection centers number n and, bacteriological testing laboratories involved in a therapeutic process.

Claim 12

Application of the process and of an information processing system used for quality management according to claim 15 to cell therapy protocols.

Claim 13

Application of the process and of an information processing system used for quality management according to claim 15 to gene therapy protocols.

Claim 14

Application of the process and of a quality management system according to claim 15, allowing ongoing training of the operator and/or the monitoring of his or her level of knowledge.

Claim 15

A method for processing information used for quality management in a therapeutic process involving several entities, including an operational entity and a preparation laboratory, this therapeutic process comprising operations of taking cells from a patient, specific treatment operations on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells treated in this way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparation (SOP) comprising a series of functional stages, ~~it~~ comprising, for each batch of samples taken from a given patient:

- after each functional stage, a stage of sequential and conditional validation of said functional stage, passing from one validation stage to a following validation stage being conditional on results of processing data collected during this validation stage and on a full completion by an operator of operational instructions within a screen page associated with said functional stage, said screen page being closed responsively to a closing order only if all said instructions have been carried out,

-a stage of processing information and data collected in the different validation stages, said collected data being associated with said batch of samples and being in particular indicative of operators and of the process state of progress, in order to issue final certification of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during this preparation, and wherein an alarm icon being provided for prompting an operator to consult a screen page listing anomalies detected during said processing stage and

a stage for inputting post-reinjection follow-up information and forwarding said information to said operational entity.

Claim 16 (previously presented)

System for processing information used for quality management in a therapeutic process involving several entities, including an operational entity, and a preparation laboratory, this therapeutic process comprising operations of taking cells from a patient, specific treatment operations on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells treated in this way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparation (SOP) comprising a series of functional stages,

comprising, for each batch of samples taken from a given patient:

for each functional stage, a means of sequential and conditional validation of said stage, passing from one validation stage to a following validation stage being conditional

on results of processing of data collected during this validation stage and on a full completion by an operation of-cooperational instructions within a screen page associated with said functional stage, said screen page being closed responsively to a closing order only if all said instructions have been carried out,

means for processing information and data collected in the different validation stages, said collected data being associated with said batch of samples and being indicative in particular of operators and of the process state of progress, in order to issue final certification of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during this preparation,

means for providing an alarm icon for prompting an operator to consult a screen page listing anomalies detected during said processing stage, and

means for inputting post-reinjection follow-up information and forwarding said information to said operational entity.